DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 5 2005

Paul Shieh, Ph.D.
President
Biomedix, Inc.
40471 Encyclopedia Circle
Fremont, CA 94538

Re: k033627
Trade/Device Name: Q.STEPS (TM) Biometer G Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CGA, JJX
Dated: February 24, 2004
Received: February 25, 2004

Dear Dr. Shieh:

This letter corrects our substantially equivalent letter of May 21, 2004 regarding the incorrect product code of CBA verses the correct product code of CGA - Glucose Oxidase, Glucose.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

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MAY 2 1 2004

510 K SUMMARY

K033627

(AS REQUIRED BY 21 C.F.R. §807.92)

Introduction:

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address:

Biomedix, Inc., U.S.A.
40471 Encyclopedia Circle
Fremont, CA 94538

Contact Person:

Judy Shieh Chen, Ph.D.
Phone:(510) 438-9500, ext.414
Fax: (510) 438-9141
E-mail: jchen@biomedixusa.com

Date Prepared:

March 29th 2004

Device Name:

Proprietary name:
Q.STEPS™ Biometer G Blood Glucose Monitoring System

Common Name:
Whole Blood Glucose Test System

Classification
1. Q.STEPS™ Biometer G and Q.STEPS™ Glucose Test Strip – Class II devices (21 C.F.R. §862.1345, Glucose Test System)
2. Q.STEPS™ Glucose Control Solution – Class I device (21 C.F.R. §862.1660, Quality Control Material)
3. Sterile lancet, Lancing Device and Accessories – Class I (exempt) devices (21 C.F.R. §878.4800, Lancet, Blood).

Classification Name:
Glucose Oxidase, Glucose

Predicate Device:

We claim substantial equivalent to the Life Scan OneTouch Basic Blood Glucose Monitoring System (Test Strips K#031472)

Intended Use:

The Q.STEPS™ Biometer G Blood Glucose Monitoring System is intended to be used for quantitative measurement of glucose in fresh capillary whole blood from the fingertip for all ages (excluding neonates.) It is intended for use outside the body (for in vitro diagnostic use) by health care professionals in settings such as clinical laboratories and physician offices laboratories (POLs) as an aid to monitor the effectiveness of diabetes control.

Test Principle:

The Q.STEPS™ Biometer G Blood Glucose Monitoring System is an in vitro device designed for measuring the concentration of glucose in capillary whole blood from the fingertip. The system uses electrochemical methodology. The system quantifies glucose amperometrically by measuring the current that is produced when glucose oxidase catalyzes the oxidation of glucose to gluconic acid. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and is converted to a readout displayed on the monitor.

Summary of Performance Studies

Safety

No adverse health effects were observed in the pre-clinical & clinical study. No post-clinical trial reports of any health effect were seen.

Linearity

The linearity of the Q.STEPS™ Biometer G System is good through a wide range of glucose concentrations, 50 to 400 mg/dl. This is confirmed with internal laboratory and external clinical studies.

Accuracy

Internal studies and clinical trial method comparison studies showed that the whole blood glucose concentrations from fingertips determined by Q.STEPS™ System correlated very well with the reference laboratory method, i.e., Yellow Spring Instrument (YSI) 2300 STST Glucose/Lactate Analyzer. All data collected fall well within the acceptance criteria of a bias within 20mg/dl (Blood Glucose <100mg/dl) or 20% (Blood Glucose ≥100mg/dl) of the reference method. Furthermore, over 98% of all clinical data fall into acceptable zones A & B in the Clarke Error Grid analysis.

Precision

Precision evaluation performed in the internal laboratory and clinical environment shows that the Q.STEPS™ System can determine very precise glucose concentrations. For commercial controls, readings were taken twice in the morning (Run1) and twice in the evening (Run2). Each reading obtained from each run was taken from two different Q.STEPS™ Biometers. This was performed every day for 20 consecutive days. For venous whole blood specimens spiked with five different concentrations of glucose, 20 readings were taken from each concentration on the same day. Overall, the standard deviation values are very low and CV values are well within the acceptance criteria of less than 8%.

Stability

In both room temperature and accelerated stability studies, the Q.STEPS™ Test Strips provide a constant glucose reading over time. From the accelerated stability evaluation, the Q.STEPS™ Test Strips have been determined to have an approximate shelf life of 2 years.

Hematocrit Interference

The degree of the hematocrit effect depends on the glucose concentration. The Q.STEPS™ System was tested within the hematocrit range from 30% to 60%. With an acceptance criteria of ±20% of the glucose concentration determined with a set of hematocrit standard (45±3%), the results of this study show that hematocrit levels of 30% to 60% is acceptable for use with the Q.STEPS™ Biometer G System.

Interference Substances

- Twenty-three commonly tested interference substances were examined in this study. No interference was observed in the Bilirubin, Cholesterol, Creatinine and Citrate at physiological levels except for Uric Acid.
- No interference was observed in the Ibuprofen, Aspirin and Tetracycline.
- No interference was observed at therapeutical ranges of Acetaminophen, Ascorbic Acid (Vit.C.), L-Dopa, Dopamine, Methyldopa and Tolazamide. Some interference was observed at higher dosages of these compounds.
- No interference was observed in EDTA (in blood drawing tubes), D-Galactose, $K_3Fe(CN)_6$, D-Mannose, D-Xylose and Maltose.

Indications for Use

510(k) Number (if known): K033627

Device Name: Q.STEPS

Indications For Use:

The Q.STEPS™ Biometer G Blood Glucose Monitoring System is intended to be used for quantitative measurement of glucose in fresh capillary whole blood from the fingertip for all ages (excluding neonates.) It is intended for use outside the body (for in vitro diagnostic use) by health care professionals in settings such as clinical laboratories and physician offices laboratories (POLs) as an aid to monitor the effectiveness of diabetes control.

Ruth A Chesler (for Carol Benson)

Division Sign-Off

Office of In Vitro Diagnostic Devi
Evaluation and Safety

510(k) K033627

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)